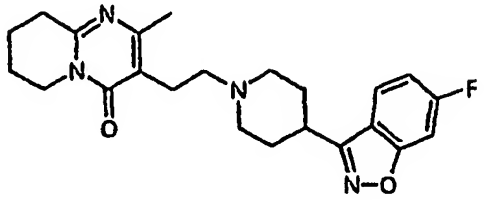
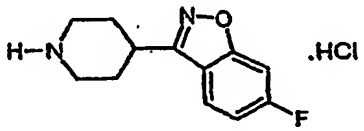
CLAIMS:

1. A process for the preparation of risperidone of Formula 1:

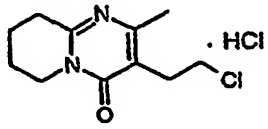


Formula -1

which process comprises reacting, in a condensation reaction, 6-fluoro-3-(4-piperidinyl)-1,2-benzisoxazole monohydrochloride of Formula -2 with 3-(2-chloroethyl)-6,7,8,9-tetrahydro–2-methyl-4H-pyrido[1,2,a]pyrimidin-4-one monohydrochloride of Formula -3 :



Formula- 2. HCl



Formula - 3. HCl

2. A process according to claim 1, wherein the condensation reaction is carried out in the presence of a base (condensing agent), in a solvent medium of water, one or more water-miscible solvents or a mixture of water and one or more water-miscible solvents, and the process comprises:

a) carrying out the condensation reaction at a temperature in the range from 25 to 90°C;

(b) after completion of the condensation reaction, diluting the condensation reaction mass with ice-cold water to precipitate risperidone;

(c) filtering and drying the precipitated risperidone to obtain crude risperidone; and

(d) crystallizing the crude risperidone in an aqueous solvent to produce pure risperidone.

3. A process according to claim 1, wherein the condensation reaction is carried out in the presence of a base (condensing agent), in a solvent medium of water, one or more water-miscible solvents or a mixture of water and one or more water-miscible solvents, and the process comprises:

a) carrying out the condensation reaction at a temperature in the range from 25 to 90°C;

(c) (b) after completion of the condensation reaction, then reaction mass is cooled to room temperature and diluting the condensation reaction mass with water to precipitate risperidone;

(c) extracting the precipitated risperidone of step (b) with a water-immiscible solvent;

(d) optionally subjecting the water-immiscible solvent extract to acid-base work-up followed by extraction with a water-immiscible solvent;

(e) concentrating the extract resulting from step (c) or optional step (d) under reduced pressure to produce crude risperidone; and

(f) crystallizing the crude risperidone in an aqueous solvent to produce pure risperidone.

4. A process according to any of claims 1 to 3, wherein the condensation reaction is carried out in a mixture of water and one or more water-miscible solvents.

5. A process according to any of claims 1 to 3, wherein the condensation reaction is carried out in water as the only solvent.

6. A process according to any of claims 2 to 4, wherein the water-miscible solvent is selected from methanol, ethanol, propanol, isopropanol, acetone, acetonitrile, dimethyl formamide, dimethyl sulfoxide, and mixtures thereof.

7. A process according to any preceding claim, wherein the condensation reaction is carried out at a temperature in the range from 40 to 90°C.

8. A process according to claim 2 or claim 3, wherein the base (condensing agent) is selected from sodium or potassium carbonate, sodium or potassium bicarbonate, and sodium or potassium hydroxide.

9. A process according to claim 8, wherein the base (condensing agent) is sodium carbonate.

10. A process according to claim 3, wherein the water-immiscible solvent is selected from dichloromethane, dichloroethane, chloroform, ethyl acetate, toluene, benzene, and mixtures thereof.

11. A process according to claim 10, wherein the water-immiscible solvent is dichloromethane.

12. A process according to claim 3, wherein the water-immiscible solvent extract is back extracted with 10-15% aqueous acid.

13. A process according to claim 12, wherein the acid is selected group from hydrochloric acid, hydrobromic acid, tartaric acid and acetic acid.

14. A process according to claim 13, wherein the acid is hydrochloric acid.

15. A process according to claim 14, wherein the pH of the aqueous acidic extract is adjusted to basic with ammonia and is further extracted into dichloromethane.

16. A process according to claim 2 or claim 3, wherein the crude risperidone is crystallized in an aqueous solvent selected from aqueous acetone, aqueous methyl ethyl ketone, aqueous methyl isobutyl ketone, aqueous acetonitrile and aqueous dimethylformamide, to produce pure risperidone.

17. A process according to claim 16, wherein the aqueous solvent is aqueous acetone.

18. A process according to any preceding claim, wherein the 3-(2-chloroethyl)-6,7,8,9-tetrahydro-2-methyl-4H-pyrido[1,2,a]pyrimidin-4-one monohydrochloride of Formula 3 is prepared starting from 3-(2-chloroethyl)-2-methyl-4H-pyrido[1,2,a]pyrimidin-4-one.

19. A process according to claim 18, wherein the 3-(2-chloroethyl)-2-methyl-4H-pyrido[1,2,a]pyrimidin-4-one is hydrogenated in the presence of a metal catalyst and hydrogen pressure.

20. A process according to claim 19, wherein the metal catalyst is Raney nickel

21. A process according to claim 20, wherein the hydrogen pressure is 70-80 psi.

22. A process according to claim 21, wherein the hydrogenation reaction temperature is 28-35

23. A process for the preparation of risperidone of Formula 1 substantially as herein described